DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-81

August 17, 1999

Larry M. LeGunn, Preident
Alpha Tron, Inc.
1925 S. W. 10th Street
Boca Raton, Florida 33486

Dear Mr. LeGunn:

We are writing to you because on June 22-25, 1999, FDA Investigator Mara S. Strier collected information that revealed serious regulatory problems involving the Acupoint stimulator, which is manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (The Act), this product is considered to be a medical device under section 201(h) of the Act because it is used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. It also requires that they conform to current good manufacturing practice requirements, as set forth in the Quality System (QS) regulation (Title 21), Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

Because you do not have marketing clearance from FDA, and have not registered your establishment or listed your product with FDA, marketing the Acupoint is a violation of the law. In legal terms, your product is misbranded under section 502(o) and adulterated under section 501(f)(1)(B) of the Act. The Acupoint is misbranded because you did not submit a premarket notification submission, as required by section

510(k), register, as required by section 510, or list the device with FDA, as required by section 510(j) of the Act.

The Acupoint is adulterated because you do not have an approved application for premarket approval in effect under section 515(a) or an approved application for an investigational device exemption under section 520(g) of the Act. These approvals are required unless you have submitted a premarket notification submission that shows that the Acupoint is substantially equivalent to other devices that are legally marketed and have been notified by FDA that you may market the Acupoint device.

The device is also adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Good Manufacturing Practice (GMP) regulation, as set forth in the Quality System (QS) regulation (Title 21), Code of Federal Regulations (CFR), Part 820, because there are no records documenting the assembly, testing, labeling and distribution of the Acupoint.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing, distribution and quality assurance systems. Also, other Federal agencies are informed about warning letters that we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to address product already in the marketplace and to prevent

this from happening again. If you need more time, let us know why and when you expect to complete your corrections.

Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 555 Winderley Place, Suite 200, Orlando, Florida 32751.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issues of premarket clearance and compliance with the QS regulation requirements and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at http://www.fda.gov.

If you have more specific questions about the Good Manufacturing Practice regulation and how it affects your particular device, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,

Douglas D. Tolen
Director, Florida District